

### DETAILED ACTION

1. The amendment filed June 15, 2009, has been entered.
2. Claims 2-11, 13, 16, 19, 22, and 25 have been cancelled.
3. Claims 1, 12, 14, 15, 17, 18, 20, 21, 23, and 24 are pending and are examined in this Office Action.

### ***Rejections that are Withdrawn***

4. The rejection of claims 1, 12, 14, 15, 17, 18, 20, 21, 23, and 24 under 35 U.S.C. 112, second paragraph, is withdrawn in light of the Applicant's amendments to the claims.
5. The rejection of claims 1, 12, 14, 15, 17, 18, 20, 21, 23, and 24 under 35 U.S.C. 112, first paragraph, for lack of scope of enablement is withdrawn in light of the Applicant's arguments and in light of reconsideration, because it would be routine experimentation to try different incubation times for different temperatures and different centrifugation times for different speeds.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 12, 14, 15, 17, 18, 20, 21, 23, and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (WO 98/54961, published December 10, 1998), in view of Lyznik et al (The Plant Journal (1995) Vol. 8; pp. 177-186). The Applicants arguments and evidence in the response filed on June 15, 2009, have been fully considered but were not found to be persuasive.

The claims are directed to a method of promoting efficiency of gene transfer via *Agrobacterium* to plant cells /tissues, comprising the steps of heating and centrifuging the plant cells, wherein the contact between the plant cells and *Agrobacterium* occurs after or while heating and/or centrifugation, and wherein the efficiency of gene transfer is increased in comparison to gene transfer to plant cells or tissues that are not heated or centrifuged. The recitation of the efficiency being increased is broadly interpreted to encompass any increase, even a 1% or 2% increase.

Hansen teaches a method of gene transfer to maize by *Agrobacterium* comprising heating the maize calli at 45°C for 4 minutes (see page 19, first paragraph). After the heat treatment, the medium was replaced by an

Agrobacterium suspension, therefore, the maize calli are contacted with Agrobacterium (see first and second paragraph on page 19). Maize plants are monocotyledons and angiosperms and belong to the family Gramineae.

Hansen does not specifically teach centrifugation from 1000G to 150,000G for 1 second to 4 hours. Hansen is silent about what particular technique was utilized to replace the medium with the Agrobacteria suspension.

Lyznik et al teach that maize protoplasts are harvested in Eppendorf tubes by centrifugation for 5-10 seconds at 1000 g (see last paragraph on page 183) and the medium was replaced with extraction buffer.

At the time the invention was made, it would have been obvious and within the scope of one of ordinary skill in the art to modify the method taught by Hansen to centrifuge the cells to facilitate changing the buffer/medium. This is an obvious variation of the method taught by Hansen, because centrifugation to settle cells into a pellet to facilitate removal of the liquid medium was well known in the art at the time of filing, as evidenced by the teaching of Lyznik et al. Furthermore, it would have been obvious to alter the exact incubation time and temperature as a normal part of process optimization, and one would expect to be able to increase the efficiency somewhat by optimizing these conditions.

The Applicant argues that the unexpected results relied on by Applicants use the same species, tissue-type and a comparable incubation period and incubation temperature to those described in Hansen (see page 9 of the response). The

Examiner agrees, and the Examiner is ready to allow claims limited in scope to the working examples in the instant specification, or limited in scope to any of the combinations of incubation times and temperatures and centrifugation times and speeds that provide superior results that have support in the originally filed specification.

The Applicant argues that the unexpected results are commensurate in scope with the instant claims (see page 10 of the response). This is not persuasive, however, because many of the combinations of times and temperatures that were provided in the Declaration filed on Oct. 24, 2008, did not produce superior results, and some of them produced less desirable results than transformation with no heating at all. Many of the combinations did not result in an increase in efficiency at all (see data points with relative GUS expression of 1), and some of the data points were actually detrimental (see 10 minutes at 49°C and 60 minutes at 46°C). However, the claims continue to encompass heating plant cells or tissues to 37°C - 52°C for 1 minute to 24 hours. Therefore, the claims are not commensurate in scope with the showing of unexpected results.

The Examiner agrees that the working examples have demonstrated unexpected results, however, the claims are not commensurate in scope with the scope of the unexpected results, because the wide range of types of plant tissue being claimed, the very wide range of temperatures and incubation times, and the very wide range of centrifugational speeds and times. The Applicant is invited to

amend the claims to recite the precise conditions utilized in the working examples, and the Examiner believes this would overcome the rejection under 35 USC 103.

The Applicant has provided Exhibit A, which is co-pending US Application No. 10/089,696; and the Examiner agrees that this overcomes the enablement rejection, however, it does not overcome the rejection under 35 USC 103(a). Most of the data are directed to centrifugation speeds of 20,000 and 40,000 x g (see pages 22-24 and 26), and the only data directed to higher speeds were carried out for 3 days and 6 days which is significantly longer than the 1 second to 4 hours of the instant claims. Therefore, the showing of unexpected results is not commensurate in scope with the claims.

Therefore, the limited showing of unexpected results is not sufficient to support the breadth of the current claims.

7. No claim is allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory

action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHY K. WORLEY whose telephone number is (571)272-8784. The examiner can normally be reached on M-F 10:00 - 4:00, with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Cathy K. Worley/  
Primary Examiner, Art Unit 1638